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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,358	09/20/2003	Craig A. Rosen	PS905	5175

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,358	ROSEN ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SDO

DETAILED ACTION

Application Status

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

2. Applicant's response to the Office Action mailed April 12, 2005 on July 12, 2005, is acknowledged.

Claim Disposition

3. Claims 2-24 have been canceled. Claim 1 is amended. Claim 1 is pending and is under examination.

Maintained-Specification Objections

4. The specification remains objected to because of the following informalities:

(a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TAQMAN®, AMPLITAQ GOLD®, for example, have been noted in this application (see page 33). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort

made to prevent their use in any manner, which might adversely affect their validity as trademarks.

(b) The specification is also objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See for example pages 30, 35 and 38. It is suggested that http:// is deleted.

Withdrawn-Specification Objections

5. Previous objection to the specification regarding the title not being descriptive is withdrawn by virtue of submission of an amendment.

Withdrawn-Objection to Claims

6. Previous objection to claim 1-4 for clarity of language is withdrawn by virtue of submission of an amendment.

Withdrawn-Claim Rejections - 35 USC ∋ 101

7. Previous rejections to claims regarding non-statutory subject matter with regard to the method steps is withdrawn by virtue of submission of an amendment.

Maintained-Claim Rejections-Utility Rejections Under 35 USC § 101 And 35 USC 112, First Paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 1 remains rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific, or well-established utility. Claim 1 is directed to an isolated polynucleotide encoding a polypeptide. The claimed polynucleotide is not supported by either a specific and substantial asserted utility or a well-established utility. The specification fails to provide objective evidence of any activity for the encoded protein. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent or implied by the specification's disclosure of the properties of a material. It is noted that page 22 of the specification indicates that the invention relates to human secreted proteins/polypeptides, and isolated nucleic acid molecules encoding said proteins/polypeptides, useful for detecting, preventing, diagnosing, prognosticating, treating and/or ameliorating cardiovascular diseases, disorders and or conditions related thereto, however, no specific association is made or demonstrated. No real association is made between a specific disorder/disease and the claimed products. A search of the claimed sequences produced a reference that teaches a fragment of the

sequence claimed (SEQ ID NO:36) that is 97.5% identical to a sequence disclosed as SEQ ID NO:12026 that comprise unknown single nucleotide polymorphism in known genes (see U.S. Patent No.6,812,339 and the alignment) which does not substantiate the claimed invention.

The specification does not disclose any particular conditions wherein there is a deficiency or overproduction of the claimed polypeptide. What disorder/disease results from a decreased expression or activity of the polypeptide, the specification does not disclose specific information. No evidence is provided, for example, that the encoded polypeptide is not expressed in healthy tissues. It could be a constitutively expressed gene, and thus would not be useful in developing drugs for any disease. Even if it were differentially expressed in disease tissues, for example, there is no indication regarding how to develop a drug to treat specific diseases, because there is no information disclosed regarding the role the polypeptide plays in healthy tissue. For example, page 26 of the instant specification state that cardiovascular diseases and disorders can be treated with the claimed proteins, however, no evidence is provided of the reduction in cardiovascular disease/disorders or the treatment of cardiovascular disease/disorders nor is there any evidence of said protein in association with cardiovascular disease. Thus, no empirical evidence exists on the record to demonstrate the association as claimed between the claimed protein and heart disease or any other diseases. The specification contains several Tables, which do not provide any evidence to demonstrate nor describe the claimed invention. A search of the encoded protein (SEQ ID NO: 549) against the DNA database produced a reference that teaches a DNA encoding a protein, that is 100% identical to the encoded protein (see attached Accession No. AAY87141), said to be useful for hepatic disease, schizophrenia, osteoporosis, AIDS, Alzheimer's disease, to name a few. The reference provides a laundry list of diseases/disorders

to which a protein that is structurally identical to the instant encoded protein is suppose to be able to treat. This demonstrates the fact that no specific disease/disorder is associated with the claimed protein. Therefore, the reference does not substantiate the instant disclosure that the encoded protein regarding the claimed protein and cardiovascular disease or any other disease or provide support for a substantial utility.

The specification asserts that the products of the invention can be used (1) as drugs for the treatment or prevention of cardiovascular disease (2) in diagnosing disease and (3) as probes. As for drugs for the treatment or prevention of cardiovascular disease, this asserted utility is not substantial. The specification does not disclose any particular conditions wherein there is a deficiency, overproduction, or altered form of the claimed polypeptides. The fact that the polynucleotide can be found in libraries of cells isolated from for example, disease tissues or immune system cells would not indicate to one of skill in the art that the protein is involved with any of the above conditions. Even if it were differentially expressed in disease tissues, for example, there is no indication regarding how to develop a drug to treat any specific disease based on the protein, because there is no information disclosed regarding the role the protein plays in healthy tissue. Significant further experimentation would be required of the skilled artisan to identify individuals who would benefit from such a drug, and then to determine a best course of treatment. There is no disclosure, for example, of how to assay for improvement or intolerable levels of side effects or dosages of the drug. Since this asserted utility is not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

It is asserted that the invention can be used in diagnosing disease with the protein, this assertion is not substantial. The specification does not disclose any specific diseases associated with altered levels or forms of the encoded protein as discussed above. Significant further experimentation would be required of one skilled in the art to identify individuals having such a disease. There is no indicia, for example, of any symptoms associated with such a disease/disorder. As this asserted utility is not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. The assertion is made of a use as probes; however, this utility is not specific, as this can be done with any polynucleotide. Expressed polynucleotides have a variety of general uses, for example, as a probe for hybridization or as a template for protein expression, these uses are applicable to any expressed polynucleotide and are not specific to the claimed polynucleotide. MPEP 2107.01 states that, "Utilities that require or constitute carrying out further research to identify or reasonably confirm 'real world' context of use are not substantial utilities".

In view of the foregoing, and absent data/evidence, the claimed invention lack utility. See *Brenner v. Manson*, 383, U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is a reward for the search, but compensation for its successful conclusion". A patent is therefore not a license to experiment. See also the Utility Guidelines available at www.uspto.gov.

9. Claim 1 remains rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well

established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Response to Arguments

10. The response filed on July 12, 2005 has been considered, however, is not fully persuasive. Note that the rejections under 35 U.S.C. 101, Utility and 35 U.S.C. 112, first paragraph for the reasons stated above, have been maintained. Applicant states that HBIAE26 polynucleotide may be involved in regulating insulin production (emphasis added) and there is no indication of how the claimed invention is involved. Applicant points to Table 1D, last column, pages 564-565 as support for the asserted function. However, a review of the Table did not provide any empirical evidence of the asserted utility, thus, the claimed invention has 'a real world' context of use, requiring further research. It is further stated that the specification teaches that the HBIAE26 polynucleotide would be useful for diagnosing and or treating diabetes mellitus, for example. Applicant concludes that the specification clearly and specifically asserts a biological role for the HBIAE26 polynucleotide and correlates this activity to specific disorders, i.e. diabetes mellitus. Thus, applicant state that the claimed invention has one patentable use for the polynucleotides of the present invention. This argument is not persuasive. The rejection of record identifies several asserted utilities, however, they are not deemed specific. Additionally, no empirical evidence is provided to demonstrate the asserted utility. The specification does not disclose any particular conditions wherein there is a deficiency or overproduction of the claimed product and its by products. The instant specification does not show that a patient suffering from a deficiency of the claimed polynucleotide or the encoding

polypeptide suffers from diabetes mellitus. What disorder/disease results from a decreased expression or activity of the product as claimed? Applicant states that the polynucleotide may be involved in regulating insulin production, (emphasis added). This assertion is not specific. Table 1D in the instant specification discusses exemplary assays and references are cited for support, however no evidence is provided of the claimed polynucleotide or the encoded polypeptide in a treatment or having the asserted function. No correlation is made between a specific disease and the claimed polynucleotide and polypeptide, the specification speculates that the claimed products may have a variety of functions. Thus, the claimed invention has not been presented in mature form, as the asserted utilities are not specific or well established. Therefore the rejection of record remains.

As the utility rejection remains the enablement rejection also remains because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility for the reasons set forth above. However, based on applicant's cancellation of the remaining claims the enablement rejection pertaining to the *In re Wands* factors has been withdrawn.

Withdrawn-Claim Rejection under 35 USC 112, First Paragraph

11. Previous rejections to claims under 35 U.S.C. 112, first paragraph written description with regard to fragment language has been withdrawn by virtue of submission of an amendment.

Withdrawn-Claim Rejection under 35 USC 112, Second Paragraph

12. Previous rejections to claims under 35 U.S.C. 112, second paragraph, with regard to definiteness is withdrawn by virtue of submission of an amendment.

Conclusion

13. No claims are allowable.

14. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS HR
Patent Examiner 9/25/05

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER